K101288
pg 1 of 2

SPINE WAVE

SEP 10 2010

510(k) Summary
StaXx® XD System

Submitter Information

Spine Wave, Inc.
Three Enterprise Drive
Suite 210
Shelton, CT 06484
Telephone: 203-712-1839
Telefax: 203-944-9493

Contact: Roaida Rizkallah
Date Prepared: May 6, 2010

Device Information

Trade Name: StaXx® XD System

Common Name: Vertebral Body Replacement

Classification: Class II per 21 CFR 888.3060

Classification Name: Spinal Intervertebral Body Fixation Orthosis

Product Code: MQP

Device Description

The StaXx® XD System is composed of wafers that are stacked into an expandable implant to adjust the height of the implant. The implant components are manufactured from PEEK-OPTIMA with 6% Barium Sulfate. The system also includes a delivery device to both implant and expand the system.

The purpose of this submission is to gain clearance for the addition of tantalum markers to the implants for added visualization under fluoroscopy.

Intended Use

The StaXx® XD System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be placed bilaterally and used with autograft or allograft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx® XD System is the CapSure® PS Spine System.

Substantial equivalence

The StaXx® XD System described in this submission is substantially equivalent in terms of design, technological characteristics, and intended use, to the following device:

Predicate Device	Manufacturer	510(k) No.
StaXx® XD System	Spine Wave, Inc.	K090315

The mechanical testing performed on the modified StaXx® XD System included dynamic axial compression and dynamic torsion per ASTM F 2077. Results of mechanical testing indicated that all acceptance criteria were met, demonstrating the StaXx® XD System's substantial equivalence to predicate device. The minor differences between the StaXx® XD System and the predicate device do not raise any new questions of safety or effectiveness. Thus, the StaXx® XD System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spine Wave, Inc.
% Ms. Roaida Rizkallah
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

SEP 10 2010

Re: K101288
Trade/Device Name: StaXx® XD System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 30, 2010
Received: August 31, 2010

Dear Ms. Rizkallah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K101288

SEP 10 2010

Device Name: StaXx® XD System

Indications for Use:

The StaXx® XD System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be placed bilaterally and used with autograft or allograft and supplemental spinal fixation. The supplemental fixation system that is intended to be used with the StaXx® XD System is the CapSure® PS Spine System.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101288